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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH, CENTRAL DIVISION

C. R. BARD, INC., a New Jersey corporation, and BARD PERIPHERAL VASCULAR, INC., an Arizona corporation, Plaintiffs, v. MEDICAL COMPONENTS, INC., a Pennsylvania corporation, Defendant.	**BARD'S MOTION FOR SUMMARY JUDGMENT INVALIDITY OF MEDCOMP'S U.S. PATENT NO. 8,021,324 PATENT** Case No. 2:12-cv-00032-RJS-DAO Judge Robert J. Shelby Magistrate Judge Daphne A. Oberg

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Plaintiffs C.R. Bard, Inc., Bard Peripheral Vascular, Inc., and Bard Access Systems, Inc. ("Bard") respectfully move pursuant to Fed. R. Civ. P. 56 for summary judgment that the Asserted Claims of U.S. Patent No. 8,021,324 ("the '324 patent") are invalid under 35 U.S.C. § 102(g) because they are anticipated by Bard's POWERPORT® M.R.I.® Implantable Port ("the PowerPort MRI").

INTRODUCTION

MedComp accuses the PowerPort MRI of infringing the '324 patent. By making this allegation, MedComp necessarily contends that the PowerPort MRI meets every limitation of the Asserted Claims. But the PowerPort MRI was made months before MedComp's earliest claimed priority date for the '324 patent. Thus, the PowerPort MRI is invalidating prior art to the '324 patent unless MedComp can satisfy its burden of producing evidence establishing that it developed the subject matter of the '324 patent before Bard's development of the PowerPort MRI. As explained below, MedComp cannot meet this burden.

MedComp's claims are invalid because it chose to assert its patent against a prior art port. The law is clear on this issue and has been for over a century. Asserting infringement against a product that turns out to be prior art supports a finding that the asserted claims are anticipated and therefore invalid. "A century-old axiom of patent law holds that a product 'which would literally infringe if later in time anticipates if earlier.'" *Upsher-Smith Labs., Inc. v. Pamlab, L.L.C.*, 412 F.3d 1319, 1322 (Fed. Cir. 2005) (quoting *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1378 (Fed. Cir. 2001)); *accord Peters v. Active Mfg. Co.*, 129 U.S. 530, 537 (1889) ("That which infringes, if later, would anticipate, if earlier."). Because the PowerPort MRI is prior art and because MedComp itself contends that the PowerPort MRI satisfies all the limitations of the Asserted Claims, those claims are invalid as anticipated.

It is undisputed that the earliest effective filing date of the '324 patent is July 19, 2007—the date the '133 provisional application was filed. There similarly is no dispute that on November 6, 2006, Bard filed its 510(k) application seeking regulatory approval to market the PowerPort MRI. Thus, there can be no serious dispute that by November 6, 2006, at the latest, Bard "made," i.e., reduced to practice, the PowerPort MRI product—in order to submit the 510(k) Bard not only made samples of the PowerPort MRI, but also used these samples to fully validate the PowerPort MRI for clinical use in humans. The FDA subsequently approved Bard's 510(k) application, thereby confirming Bard's conclusion that the PowerPort MRI worked for its intended purpose.

Given these undisputed dates, the PowerPort MRI presumptively is prior art under 35 U.S.C. § 102(g), and the only way for MedComp to avoid summary judgment is to come forward with evidence showing either: (1) that MedComp reduced the subject matter of the '324 patent to practice before Bard's reduction to practice date; or (2) that MedComp conceived of the subject matter of the '324 patent before Bard's date and that MedComp worked diligently to reduce the invention to practice. MedComp has failed to come forward with evidence creating genuine issues of fact that would stave off summary judgment.

First, MedComp alleges it constructively reduced the subject matter of the '324 patent to practice on October 18, 2006, when it filed a different provisional patent application, the '591 provisional, ***which is not part of the priority claim for the '324 patent***. However, provisional applications outside of a patent's priority chain cannot evidence a constructive reduction to practice. Thus, MedComp cannot, as a matter of law, rely on the '591 provisional to avoid summary judgment.

Second, MedComp alleges an earlier conception date and diligence through the July 19, 2007 filing date of the '133 provisional. However, reasonable diligence must be shown "throughout the entire critical period, which begins just prior to the competing reference's effective date and ends on the date of the invention's reduction to practice." *Perfect Surgical Techniques, Inc. v. Olympus Am., Inc.*, 841 F.3d 1004, 1007 (Fed. Cir. 2016). Although Bard disputes MedComp's alleged conception dates, the Court need not even consider that issue to properly grant summary judgment here because MedComp cannot show diligence throughout the entire critical period as a matter of law. When asked during discovery to identify all of its diligence evidence, MedComp came forward with evidence of diligence on only nine days for the 257 day period from November 5, 2006 (just prior to Bard's reduction to practice) to July 19, 2007 (the filing of the '133 provisional). In fact, MedComp has no diligence evidence at all for the three month period from November 9, 2006 to February 15, 2006. Drawing all inferences in MedComp's favor, no reasonable factfinder could determine that this evidence meets the legal standard for diligence. Indeed, Federal Circuit case law is clear that gaps shorter than MedComp's are not sufficient. *See In re Meyer Mfg. Corp.*, 411 F. App'x 316, 319–20 (Fed. Cir. 2010) (finding diligence evidence insufficient where, even with that evidence, "Meyer is left with an unexplained gap of just over two months").

Accordingly, the Court should enter summary judgment that the PowerPort MRI anticipates all of the Asserted Claims under 35 U.S.C. § 102(g).

RELIEF SOUGHT

Bard seeks summary judgment that claims 1, 19-20, 26 and 39-42 ("the Asserted Claims) of the '324 patent are invalid under 35 U.S.C. § 102(g) because they are anticipated by Bard's POWERPORT® M.R.I.® Implantable Port.

BACKGROUND OF THE TECHNOLOGY

The '324 patent is directed to an allegedly novel venous/vascular access port. Venous access ports are a type of medical device used to access a central artery or vein to deliver medication or other fluids without the need for an intravenous line. As the '324 patent acknowledges, such ports were "well-known" prior to the filing of the '324 patent and the '324 patent is limited to the specific ports described and claimed in that patent. Ex. A at 1:19.

Referring to Figure 1, the '324 patent explains that a port contains a housing **12**, a septum **14**, and a discharge port **16**:

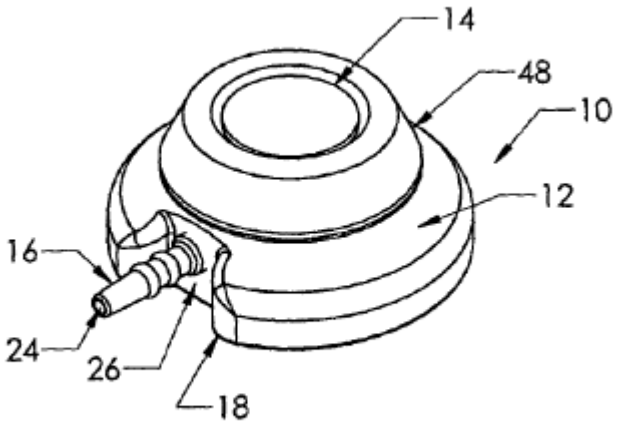

FIG. 1

Id. at 3:1-2. The port is implanted subcutaneously, typically in either the chest or the arm, and a catheter (a tubing) is attached to the discharge port on one end and inserted into a patient's central artery or vein on the other end. *See id.* 3:1-5. Liquids can then be either infused or withdrawn by using a needle to penetrate the skin and the septum and inject or withdraw liquid from a central cavity of the port.

Figure 4 of the '324 patent provides a cross sectional view that shows the interior of the port. The '324 patent explains that "[h]ousing **12** is shown to include a housing base **28** of

needle-impenetrable material that includes a well **30** having a bottom floor **32** and side walls **34** that define the interior reservoir **22** beneath septum **14**":

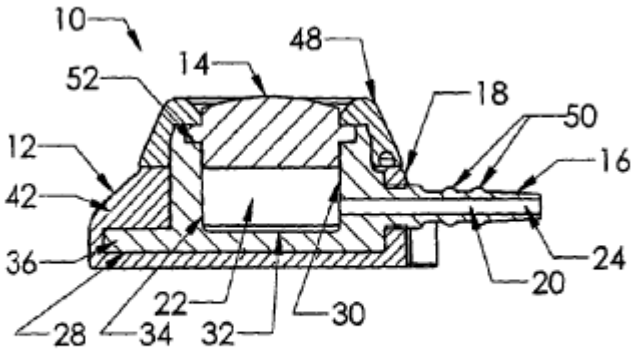

FIG. 4

Id. at 3:17-20. The '324 patent further explains that the housing base 28 has a "bottom wall **44**" and "a bottom outer surface **54**." *Id.* at 3:29-31, 3:3:49.

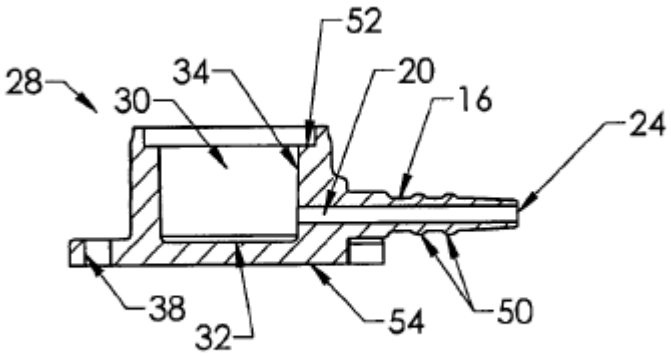

FIG. 7

The alleged invention of the '324 patent is "the incorporation of X-ray discernable indicia" onto the bottom surface or into the bottom wall of a venous access port "that is discernible under X-ray examination to provide information concerning the nature or key attribute of the venous access port." *Id.* at 1:47-51. These markings can be viewed under X-ray by a practitioner subsequent to port implantation. *Id.* at 1:51-52. An embodiment of the patent is Figure 12 "in

which the disc 100 of Fig. 8 is embedded within the thickness of the bottom wall 130 of the housing base 132." *Id.* at 4:2-4.

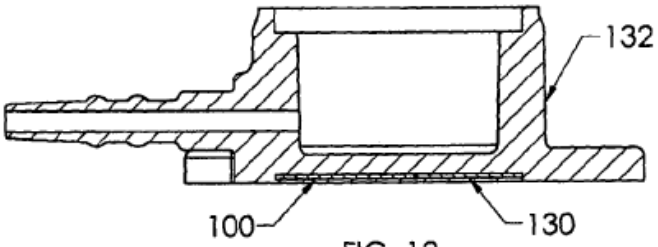

FIG. 12

STATEMENT OF UNDISPUTED MATERIAL FACTS

I. MEDCOMP'S '324 PATENT

1. The '324 patent is directed to a "Venous Access Port With X-Ray Discernable Indicia" and claims priority to Provisional Patent Application No. 60/961,133 ("the '133 provisional"), filed on July 19, 2007. *Id.* at Cover Page.

2. The '324 patent does not claim priority to Provisional Patent Application No. 60/852,591. *Id.*

3. The '324 patent identifies three inventors: Raymond Bizup, Kevin Sanford, and Christopher Linden. *Id.*

4. The '324 patent contains three independent claims, claims 1, 19, and 28, but MedComp does not assert claim 28 in this litigation.

5. Independent claim 1 contains the following language:

> a housing comprising
>
> a housing base having a bottom wall and
>
> X-ray discernable indicia embedded in the bottom wall,
>
> the X-ray discernable indicia comprising one or more characters that visually indicate, under X-ray examination, a pressure property of the port assembly.

Id. at 4:40-42.

6. Independent claim 19 contains the following language:

> a housing comprising
>
> a housing base comprising a bottom wall and
>
> radiopaque indicia embedded in the bottom wall of the housing base
>
> the radiopaque indicia comprising one or more characters indicating a pressure property of the port assembly under X-ray examination . . . .

Id. at 5:42-44.

7. MedComp also is asserting dependent claims 20, 26, and 39-42. Because each of these dependent claims depends from claim 1 or 19, every asserted dependent claim also requires:[1]

> a housing comprising
>
> a housing based having or comprising a bottom wall and
>
> radiopaque or X-ray discernable indicia embedded in the bottom wall
>
> the radiopaque or X-ray discernable indicia comprising one or more characters that indicate a pressure property of the port assembly under X-ray examination.

See id. at 4:40-42, 5:42-44 .

[1] Dependent claims refer back to and further limit an independent claim, thus every element required by the independent claim is also required by its dependent claims. 37 CFR § 1.75(c).

II. MEDCOMP'S U.S. PATENT PROVISIONAL APPLICATION NO. 60/852,591

8. U.S. Provisional Patent Application No. 60/852,591 (the '591 provisional") was filed on October 18, 2006, and is directed to a "Venous Access Port Assembly with Radiopaque Indicia." Ex. B at Cover Page.

9. The '591 provisional identifies four inventors: Raymond Bizup, Kevin Sanford, Kenneth Zinn, and Timothy Schweikert. *Id.* at Application Cover Page.

10. The '591 provisional discloses, among other things, that "[r]adiopaque indicia 70 are provided on bottom outer surface 54 within the region directly beneath the reservoir and septum. In the example shown [in Figure 10], indicia 70 comprise the letters 'CT' representing the term 'computed tomography.'" *Id.* at 5:20-6:12 (also referred to as [0020]).

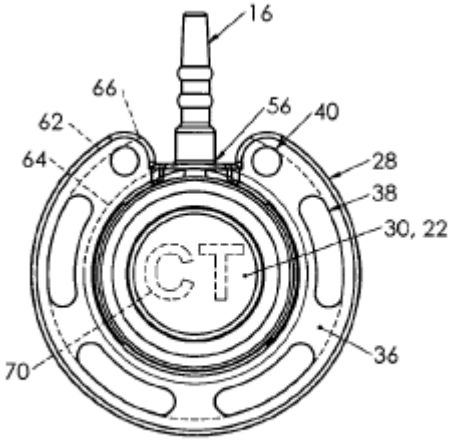

FIG. 10

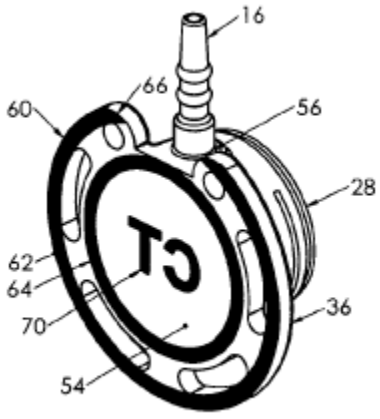

FIG. 8

11. The '591 provisional provides further:

> The radiopaque markings and indicia would appear on an X-ray of the patient, and the indicia are provided upside-down on the bottom outer surface of the housing base so that the indicia would appear right-side-up when the X-ray is viewed Centering of the indicia within the region (identified as "30, 22" in FIG. 10) directly beneath the reservoir and septum minimizes any obscuring by the structure of the venous access port assembly, and the indicia may also be easily discernable should the port assembly be at an angle from the horizontal plane of the X-ray. The outer and inner circles

> 62, 64 would appear oval or elliptical should the port assembly be at such an angle.

Id.

12. The '591 provisional also states that "[t]he radiopaque markings may alternatively applied [sic] to the inwardly facing surface of the bottom wall of the housing base, or may constitute foil or film (such as a decal) of radiopaque material embedded within the housing base, these alternatives not being shown in the drawings." *Id.* at 6:20-22 (also referred to as [0022]).

13. Claim 1, the only independent claim, contains the following language:

> A venous access port assembly for implantation into a patient, comprising:
>
> > a housing having a discharge port, a needle-penetrable septum and a cap securable to the housing and retaining the septum securely in the assembly, the housing having a housing base defining the bottom wall of the reservoir, with the housing base having an outwardly facing bottom surface, and
> >
> > the housing base including radiopaque markings, the markings including indicia that indicate an attribute of the assembly when an X-ray of the patient is taken so that the practitioner can be advised of the attribute of the assembly after implantation.

Id. at Claim 1.

III. ALLEGATIONS REGARDING CONCEPTION AND REDUCTION TO PRACTICE OF THE '324 PATENT

14. Bard served its Third Set of Interrogatories (Nos. 8-9) on MedComp on July 17, 2020. Ex. C.

15. Interrogatory No. 9 asked MedComp for the following information:

> For each asserted claim of the '324 patent, state: 1) the date that you contend the alleged invention recited by the claim was first conceived and provide a claim chart identifying on a claim

> limitation-by-claim limitation basis each document that you intend to rely on to support the alleged conception date; 2) the date that you contend the alleged invention recited by the claim was first reduced to practice and provide a claim chart identifying on a claim limitation-by-claim limitation basis each document that you intend to rely on to support the alleged reduction to practice; and 3) identify every document that you intend to rely to support your alleged diligence for the entire period from the first alleged conception to the first alleged reduction to practice.

Id. at 8.

16. MedComp served its first response to Bard's interrogatory on August 17, 2020, which it proceeded to supplement three additional times until it served its Fourth Amended and Supplemental Responses to Bard's Third Set of Interrogatories (Nos. 8-9) on February 8, 2021. Ex. D.

17. In response to Bard's Interrogatory No. 9, MedComp provided a chart with the dates by which it contends that the invention recited in each asserted claim of the '324 patent was conceived and reduced to practice. *Id.* at 9-25. MedComp also stated that the chart "identifies on a claim-element-by-claim-element basis, documents on which MedComp intends to reply to support the conception and reduction to practice dates identified." *Id.* at 9.

18. [redacted]

22. [redacted]

[redacted] [redacted]

[redacted] [redacted]

[redacted] [redacted]

26. [redacted]

[redacted]

28. On September 14, 2020, Bard served a Notice of Deposition of Medical Components, Inc., pursuant to Rule 30(b)(6). Ex. M.

29. Topic 1 of Bard's 30(b)(6) Deposition Notice asked MedComp to designate a witness competent to testify about:

> The conception and reduction to practice of the subject matter claimed in the '324 patent, including the date on which the subject matter was conceived, the date on which the subject matter was reduced to practice, and any diligence between the conception date and the reduction to practice date and all evidence supporting conception, reduction to practice and diligence.

Id. at 7.

30. And Topic 18 of Bard's 30(b)(6) Deposition Notice asked MedComp to designate a witness competent to testify regarding:

> MedComp's responses and supplemental responses to Bard's discovery requests in this matter, including but not limited to the factual bases and support for MedComp's responses to Bard's interrogatories and requests for admission.

Id. at 9.

31. Thereafter, MedComp designated Mr. Raymond Bizup to testify regarding Topic 1, and Mr. Timothy Schweikert to testify regarding Topic 9. *See* Ex. N, Bizup Dep. Tr. at 14:10-15; Ex. O, Schweikert Dep. Tr. at 78:3-19.

32. [redacted]

IV. BARD'S POWERPORT MRI

36. Bard manufactures, sells, and markets the POWERPORT® M.R.I.® Implantable Port ("PowerPort MRI") under clearance from the FDA pursuant to K063377. Ex. Q. The 510(k) premarket notification to market the PowerPort MRI was submitted to the FDA on November 6, 2006. *Id.*; *see also* Ex. R ¶ 25. By that time, Bard had functioning PowerPort MRI prototypes that had completed feasibility and qualification testing, and had been shown to work

for their intended purpose. Ex. R ¶ 25; *see also* Ex. Q at BARD_MEDCOMP_00278668-715 [redacted] Bard's 510(k) submission for the PowerPort MRI was cleared by the FDA on January 25, 2007. Ex. Q.

37. [redacted]

[redacted]

[redacted]

40. [redacted]

[redacted]

42. After Bard received FDA approval to market the PowerPort MRI, physical samples of the PowerPort MRI were publicly made available to persons involved with access port technology beginning February 2007. Ex. U ¶ 29.

43. [redacted]

[redacted]

45. Finally, the PowerPort MRI was sold, i.e., shipped, in the United States no later than March 23, 2007. Ex. U ¶ 32; *see also* Ex. v. at 2-5 (showing orders billed for the PowerPort MRI throughout March 2007). [redacted]

46. In its Amended Answer and Counterclaims ("FAAC"), MedComp accused the PowerPort MRI of infringement. Ex. Y.

47. Specifically, it alleged, *inter alia*, that:

> Bard has infringed, and continues to infringe, literally or under the doctrine of equivalents, the '324 patent by making, using, selling, offering for sale within the United States, and/or importing into the United States, products that are covered by one or more claims of the '324 patent. Such products include venous access ports with x-ray discernable indicia including, for example, PowerPort MRI Implantable Port, PowerPort isp MRI Implantable Port, and PowerPort duo MRI Implantable Port.

Id. ¶66.

48. MedComp also made allegations in its initial and final infringement contentions that the PowerPort MRI infringed each limitation of each asserted claim of the '324 patent. *See* Ex. Z; Ex. AA. Specifically, it attached claim charts to both its initial and final infringement contentions purportedly demonstrating how the PowerPort MRI meets each and every limitation of every asserted claim of the '324 patent. *See* Ex. Z at Ex. A; Ex. AA at Ex. A.

ARGUMENT

I. LEGAL STANDARDS

A. Summary Judgment

A party is entitled to summary judgment where there is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Warner Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39 & n.8 (1997); *PSN Illinois, LLC v. Ivoclar Vivadent, Inc.*, 525 F.3d 1159, 1166-68 (Fed. Cir. 2008). Conclusory allegations are insufficient to defeat a motion for summary judgment; the non-movant cannot rest on mere allegations or denials but must set forth specific facts showing that a genuine issue of material fact exists. Fed. R. Civ. P. 56(e); *Celotex Corp. v. Catrett*, 477 U.S. 317, 324 (1986).

B. Patent Invalidity

"[A] claim is anticipated if each and every limitation is found either expressly or inherently in a single prior art reference." *Bristol-Myers*, 246 F.3d at 1374 (alteration in original). This test mirrors, to some extent, the test for infringement, and "it is axiomatic that that which would literally infringe if later anticipates if earlier." *Id.* at 1378. The party challenging validity bears the burden of establishing invalidity by clear and convincing evidence. 35 U.S.C. § 282. However, "[w]hile anticipation is a question of fact, it may be decided on summary judgment if the record reveals no genuine dispute of material fact." *Encyclopaedia Britannica, Inc. v. Alpine Elecs. of Am., Inc.*, 609 F.3d 1345, 1349 (Fed. Cir. 2010) (internal citation omitted). This is particularly true where the product accused of infringement is, in fact, prior art. *See Evans Cooling Sys., Inc. v. General Motors Corp*., 125 F.3d 1448, 1451 (Fed. Cir. 1997) ("Although [defendant] bore the burden of proving that the [allegedly infringing product] embodied the patented invention or rendered it obvious for purposes of the summary judgment motion, this burden is met by [plaintiff's] allegation, forming the sole basis for the complaint,

that the [allegedly infringing product] infringes.''); *Teva Pharms. Indus. Ltd. v. AstraZeneca Pharms. LP*, 661 F.3d 1378, 1382 (Fed. Cir. 2011) (same).

Prior art is defined by 35 U.S.C. § 102.[2] Under § 102(g), a patent is invalid if "the [claimed] invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it." In determining priority of an invention under § 102(g), courts must consider "not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other." 35 U.S.C. § 102(g). "Reasonable diligence must be shown throughout the entire critical period, which begins just prior to the competing reference's effective date and ends on the date of the invention's reduction to practice." *Perfect Surgical*, 841 F.3d at 1007.

II. BARD'S POWERPORT MRI ANTICIPATES THE ASSERTED CLAIMS OF THE '324 PATENT

The Court should grant summary judgment of invalidity of the Asserted Claims of the '324 patent because those claims are anticipated by Bard's PowerPort MRI port under 35 U.S.C. §102(g). MedComp accuses the PowerPort MRI of infringing these claims and has made explicit factual assertions in its Complaint, as well as its initial and final infringement contentions, that the PowerPort MRI meets every limitation of the Asserted Claims. Thus, there is no dispute that, at least under MedComp's interpretation and application of the Asserted Claims, the PowerPort MRI satisfies every limitation of the Asserted Claims.[3]

---

[2] Section 102 has been amended by the America Invents Act ("AIA"). Those amendments do not apply to MedComp's '324 patent because its priority date pre-dates the AIA.

[3] For purposes of this motion, Bard accepts MedComp's "necessary interpretation of the scope" of the claims, as inferred from "its charge of infringement" that the PowerPort MRI infringes claims 1, 19-20, 26 and 39-42 of the '324 patent. *See Evans Cooling*, 125 F.3d at 1451

However, there is no genuine dispute that the PowerPort MRI was reduced to practice by, at the absolute latest, November 6, 2006, when Bard submitted its 510(k) application seeking the FDA's approval to market the PowerPort MRI.[4] Bard's reduction to practice date is at least eight months before the July 19, 2007 effective filing date of the '324 patent MedComp has claimed. Thus, the PowerPort MRI is prior art unless MedComp can establish either an earlier reduction to practice, or an earlier conception date combined with diligence in reducing its invention to practice.

As explained in detail below, MedComp's discovery responses and corporate deposition testimony confirm that MedComp cannot establish either an earlier reduction to practice or diligence. Thus, all the Court needs to do to grant summary judgment of invalidity is to apply the patent law maxim: "That which infringes, if later, would anticipate, if earlier." *Peters*, 129 U.S. at 537; *see also Teva*, 661 F.3d at 1385 (holding that, because of patent holder's allegations, "this case does not involve a factual dispute about whether or not the prior art includes a certain claim limitation").

A. MedComp Alleged That The PowerPort MRI Satisfies All Of The Limitations Of Claims 1, 19-20, 26, and 39-42

In its counterclaims, and again in both its preliminary and final infringement contentions, MedComp alleged that the PowerPort MRI met all of the asserted claims of the '324 patent. *See* Statement of Undisputed Material Fact ("SUMF") 46-48; Ex. Y ¶ 66; Ex. Z; Ex. AA.

("Although [defendant] bore the burden of proving that the [allegedly infringing product] embodied the patented invention or rendered it obvious for purposes of the summary judgment motion, this burden is met by [plaintiff's] allegation, forming the sole basis for the complaint that the [allegedly infringing product] infringes.''). Nothing in this motion should be construed as an admission that the PowerPort MRI infringes any claim of the '324 patent.

[4] In fact, Bard reduced the PowerPort MRI months earlier, but Bard, for purposes of this motion, Bard is relying on its 510(k) submission to establish actual reduction to practice.

In Exhibit A to its initial and final infringement contentions, MedComp alleged that the PowerPort MRI met every Asserted Claim of the '324 patent. Ex. Z at Ex. A; Ex. AA at Ex. A. For example, it alleged specifically in its final infringement contentions that the PowerPort MRI satisfied every element of claim 1 of the '324 patent. Ex. AA, Ex. A at 1-8. MedComp made similar allegations for every element of claim 19, as well as all of the elements of each asserted dependent claim. *See id.* at 10-19; *see also id.* at 1-32.

The factual allegations in MedComp's Amended Answer and Counterclaims are binding judicial admissions for purposes of this motion. "Statements made in pleading are considered judicial admissions and are 'conclusively binding on the party who made them.' Thus, absent evidence to the contrary, the Court will accept as true the facts Plaintiffs alleged in their complaint in the underlying lawsuit." *Labertew v. Chartis Prop. Cas. Co.*, 363 F. Supp.3d 1031, 1041 (D. Ariz. 2019) (citation omitted) (quoting *Christian Legal Soc. v. Martinez*, 561 U.S. 661, 716 (2010) (Alito, J., dissenting)); *see also MNM Inv., LLC v. HDM, Inc.*, No. 18-1267-EFM-KGG, 2019 WL 3801672, at *7 (D. Kan. Aug. 13, 2019) ("A statement or assertion of fact in a complaint or other pleading may serve as a judicial admission."). Moreover, "[a] judicial admission is conclusive, unless the court allows it to be withdrawn. . . . ." *Koch v. Koch Indus., Inc.*, 996 F. Supp. 1273, 1277 (D. Kan. 1998) (quoting Keller v. United States, 58 F.3d 1194, 1198 n.8 (7th Cir. 1995)).

Similarly, the allegations made in MedComp's infringement contentions are also binding admissions for purposes of this motion. *See Vanmoor v. Wal-Mart Stores, Inc.*, 201 F.3d 1363, 1366 (Fed. Cir. 2000) (upholding summary judgment of invalidity where, "[a]lthough Wal-Mart and the manufacturers bore the burden of proving that the cartridges that were the subject of the pre-critical date sales anticipated the '331 patent, that burden was satisfied by Vanmoor's

allegation that the accused cartridges infringe the '331 patent."); *see also Gammino v. Sprint Commc'ns Co. L.P.*, No. 10-2493, 2011 WL 3240830, at *2 (E.D. Pa. July 29, 2011) (same).

Thus, MedComp's allegations of literal infringement necessarily mean that MedComp is bound by its repeated contentions that the PowerPort MRI meets all of the limitations of claims 1, 19-20, 26 and 39-42 of the '324 patent. There is no factual dispute that the PowerPort MRI meets all the limitations of the asserted claims of the '324 patent.

B. The PowerPort MRI is Prior Art Under 35 U.S.C. § 102(g)

Given MedComp's admission that the PowerPort MRI meets every limitation of the Asserted Claims, the PowerPort MRI anticipates these claims if it is prior art to the '324 patent.

Under § 102(g), a product is prior art if the claimed invention "has been made by another, prior inventor who has not abandoned, suppressed, or concealed the invention." *Fox Grp., Inc. v. Cree, Inc.*, 700 F.3d 1300, 1304 (Fed. Cir. 2012). A prior inventor challenging a patent under § 102(g) has two ways to prove its prior invention: (1) it can show that "it reduced its invention to practice first"; or (2) it can show "it was the first party to conceive of the invention and then exercised reasonable diligence in reducing that invention to practice." *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316, 1332 (Fed. Cir. 2001).

1. Bard's Prior Reduction to Practice of the PowerPort MRI

There is no genuine issue of fact that Bard's PowerPort MRI was both reduced to practice prior to the July 19, 2007 effective filing date of the '324 patent. To establish reduction to practice, "the prior inventor must have (1) constructed an embodiment or performed a process that met all the claim limitations and (2) determined that the invention would work for its intended purpose." *Teva*, 661 F.3d at 1383.

On November 6, 2006, Bard submitted a 510(k) application to the FDA seeking approval to sell the PowerPort MRI. SUMF 36; Ex. Q. Thus by November 6, 2006, Bard had not only

made samples of the PowerPort MRI, but had used these samples to fully validate the PowerPort MRI for clinical use in humans, i.e. it worked for its intended purpose. SUMF 36-42; Ex. R ¶ 25. Bard's 510(k) application includes, *inter alia*, [redacted] SUMF 36; Ex. Q at BARD_MEDCOMP_00278668-715; *see also* Ex. R ¶¶ 24-25. The FDA approved the 510(k) application as submitted on January 25, 2007. SUMF 42; Ex. Q at BARD_MEDCOMP_000278601. Thus, the medical device that Bard has legal approval to sell in the U.S. is fully described in the 510(k) that was submitted on November 6, 2006, and by the date of the 510(k) submission, Bard had "functioning POWERPORT® M.R.I.® Implantable Port prototypes that had completed feasibility and qualification testing." Ex. R at ¶ 25; *see also* Ex. R ¶ 26. Thus, there can be no dispute that Bard actually reduced the subject matter covered by the Asserted Claims to practice by November 6, 2006, eight months before MedComp's July 19, 2007 effective filing date of the '324 patent. *See Scott v. Finney*, 34 F.3d 1058, 1063 (Fed. Cir. 1994) (explaining that, in fact, "[t]esting for the full safety and effectiveness of a prosthetic device" by the FDA exceeds what is required to prove reduction to practice).

2. MedComp Cannot Antedate Bard's Earlier Reduction to Practice of the PowerPort MRI

To remove the PowerPort MRI as a prior art reference, MedComp must prove an earlier reduction to practice or earlier conception date and reasonable diligence in reducing to practice throughout the entire critical period, "which begins just prior to the competing reference's effective date and ends on the date of the invention's reduction to practice." *Perfect Surgical*, 841 F.3d at 1007. "Stated otherwise, priority of invention 'goes to the first party to reduce an invention to practice unless the other party can show that it was the first to conceive the

invention and that it exercised reasonable diligence in later reducing that invention to practice.'" *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1576 (Fed. Cir. 1996) (quoting *Price v. Symsek*, 988 F.2d 1187, 1190 (Fed. Cir. 1993)). Significantly, although it is Bard's burden to demonstrate that the PowerPort MRI is prior art to the '324 patent, once Bard demonstrates that the Power Port MRI was reduced to practice before to the priority date of the '324 patent, "the burden of production shifts to the patent owner to produce sufficient rebuttal evidence to prove entitlement to an earlier invention date." *Taurus IP, LLC v. DaimlerChrysler Corp.*, 726 F.3d 1306, 1322 (Fed. Cir. 2013); *see also Mahurkar*, 79 F.3d at 1577. As a matter of law, MedComp cannot meet this burden.

Here, MedComp alleges an earlier reduction based upon the October 16, 2006 filing date of the '591 provisional patent application, to which the '324 patent does ***not*** claim priority. SUMF 18-19; Ex. D at 10-26. In the alternative, MedComp alleges an earlier conception coupled with reasonable diligence for the period up to the July 19, 2007 filing date of the '133 provisional patent application, to which the '324 patent does claim priority. SUMF 20-21; Ex. D at 10-26. As explained below, MedComp cannot as a matter of law rely on the October 16, 2006 filing date of the '591 provisional application because the '324 patent does not claim priority to that application. Moreover, even accepting MedComp's alleged earlier conception, MedComp cannot as a matter of law establish diligence for the entire period leading up to the July 19, 2007 filing of the '133 provisional.

(a) MedComp Cannot Rely on the '591 Provisional Application For Constructive Reduction to Practice

As noted above, MedComp alleges that it constructively reduced the subject matter of the '324 patent to practice by October 16, 2006 when it filed the '591 provisional patent application. As a matter of law, however, MedComp is not entitled to a constructive reduction to practice

date before July 19, 2007, the priority date of the '324 patent, because the '591 provisional is outside of the chain of priority identified on the face of the '324 patent. Ex. A at (60).

Constructive reduction to practice is a judicially-created doctrine that allows inventors to evidence a reduction to practice by filing a patent application on their invention instead of creating a physical embodiment of their invention. *See Hyatt v. Boone*, 146 F.3d 1348, 1352 (Fed. Cir. 1998) ("The filing of a patent application serves as conception and constructive reduction to practice of the subject matter described in the application."). The doctrine is based on the presumption that the filing date of the application from which a patent issues is the invention date, because, in order to issue as a patent, an application must "describe the claimed subject matter . . . in terms that establish that [the applicant] was in possession of the . . . claimed invention, including all of the elements and limitations." *Hyatt*, 146 F.3d at 1353; *see also Bates v. Coe*, 98 U.S. 31, 34 (1878) (explaining that the doctrine of constructive reduction to practice is based on the presumption that "the invention described in the patent in suit, if it is accompanied by the application for the same, . . . was made at the time the application was filed").

In modern patent law, however, patent applications can claim the benefit of an earlier filing date of a provisional application, termed "claiming priority" to an earlier filed provisional application. *See* 35 U.S.C. § 119 (entitled, "Benefit of Earlier Filing Date; Right of Priority"). In such cases, the filing date of the provisional becomes the presumed date of invention, and thus the presumed constructive reduction to practice date, but only so long as the applicant meets the requirements for claiming priority as set forth in 35 U.S.C. § 119(e). *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) ("For a patent to claim priority from the filing date of its provisional application, it must satisfy 35 U.S.C. § 119(e)(1) (2006)."); *Stevens v. Tamai*, 366 F.3d 1325, 1331 (Fed. Cir. 2004) ("'The effective filing date of

an application is the filing date of an earlier application, benefit of which is accorded to the application under 35 U.S.C. 119, 120, 121, or 365 . . . .'") (internal citations omitted)[5]; *see also Goeddel v. Sugano*, 617 F.3d 1350, 1353-54 (Fed. Cir. 2010) (explaining that an invention for which the priority of another "patent application is available in accordance with treaty and statute may rely on the content of the [other] application for constructive reduction to practice").

Section 119 requires, among other things, that the application for patent be "filed ***not later than 12 months after the date on which the provisional application was filed"*** and that "it contain[] or is amended to contain ***a specific reference to the provisional application***." 35 U.S.C. § 119(e)(1) (emphasis added). Further, it states that "[n]o application shall be entitled to the benefit of an earlier filed provisional application under this subsection unless an amendment containing the specific reference to the earlier filed provisional application is submitted at such time during the pendency of the application as required by the Director." *Id.*; *see also* 37 C.F.R. § 1.78(a)(5)(i), (ii) (2005) (pre-AIA).

Therefore, as a matter of law, in order to rely on a constructive reduction to practice based on an earlier-filed provisional application, a patent must claim priority to that provisional application. And in order to claim priority to an earlier-filed provisional application, the application for patent must, among other things, be filed within a year of the provisional's filing date, and contain, or be amended to contain during the its pendency, a specific reference to that provisional application. There is no dispute that the application giving rise to the '324 patent

[5] An interference proceeding also applies § 102(g). The Federal Circuit has interpreted the requirements under § 102(g) consistently for district court actions and interference proceedings. *Apotex USA, Inc. v. Merck & Co.*, 254 F.3d 1031, 1037 (Fed. Cir. 2001) ("A § 102(g) prior invention defense is governed by the identical 'suppressed or concealed' language applicable to priority determinations in interference proceedings. We must therefore interpret the § 102(g) defense provision consistently with established interference law.") (citations omitted).

was filed more than 12 months after the date on which the provisional application was filed. *Compare* Ex. A (filed on of July 17, 2008), *with* Ex. B at Application Cover Sheet (filed on July 17, 2008). And, of course, there is no dispute that the application giving rise to the '324 patent is no longer pending; it issued as the '324 patent on September 20, 2011. Ex. A. Finally, there is also no dispute that the '324 patent does not contain a specific reference to the '591 provisional. In fact, the '324 patent contains a specific reference to an entirely separate provisional application. *See* Ex. A at (60). The '324 patent lists no other patents or applications in its priority chain. *Id.* Those failures preclude MedComp from priority to the '591 provisional. *Encyclopaedia Britannica*, 609 F.3d at 1352 (holding that an application "is not entitled to the priority date" of an earlier application where it "failed to specifically reference the earlier filed . . . application" in the priority chain).[6]

Thus, as a matter of law, the '591 provisional cannot constitute a constructive reduction to practice of the invention disclosed by the asserted claims of the '324 patent. *See Fried v. Murray*, 267 F.2d 326, 327 (C.C.P.A. 1959) ("[U]nless there was continuity of prosecution of the subject matter here in issue between the filing dates of the applications on which the earlier and later patents to Murray et al. were granted, that party cannot be awarded priority on the basis of a constructive reduction to practice as of the filing date of the earlier application.").[7]

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[6] In *Encyclopaedia*, the court's holding was focused 35 U.S.C. § 120, which governs the requirements for establishing the benefit of an earlier filed ***non***-provisional patent application. That holding is equally applicable to § 119 though because the two sections contain identical language regarding the necessary specific reference. *Compare* § 120 ("[i]f it contains or is amended to contain a specific reference to the earlier filed application."), *with* § 119 ("[I]f it contains or is amended to contain a specific reference to the provisional application.").

[7] *See also Powell v. Poupitch*, 167 F.2d 514, 517 (C.C.P.A. 1948) ("[A]n application by one inventor cannot inure to the benefit of another even though the applications have a common assignee."); *Coleman v. Dines*, 754 F.2d 353, 359 (Fed. Cir. 1985) ("The Board then correctly pointed out that the filing date of the Coleman and Marks '829 application may not be relied

(b) MedComp Cannot Establish Diligence Leading Up to the Filing of the '133 provisional

Because it is legally precluded from relying on the filing date of the '591 provisional, the earliest constructive reduction to practice date that MedComp can establish is July 19, 2007—the filing date of the '133 provisional application. *See* Ex. A at (60). However, because this date is after Bard's reduction to practice date, the only way that MedComp can remove Bard's PowerPort MRI as prior art under §102(g) is to show that it was diligent in reducing its alleged prior invention to practice. More specifically, to meet its burden of production, MedComp must show diligence from a date just before the date of reduction to through filing of the '133 provisional on July 19, 2007. *See ATI Techs. ULC v. Iancu*, 920 F.3d 1362, 1370 (Fed. Cir. 2019) ("The burden of proving diligence is on the party asserting the benefit of diligent activity . . . .").

To show diligence, it must demonstrate that "there was reasonably continuing activity to reduce the invention to practice." *Brown v. Barbacid*, 436 F.3d 1376, 1380 (Fed. Cir. 2006). And while there does not need to be evidence of activity on every single day if a satisfactory explanation is evidenced, "[m]erely asserting diligence is not enough; a party must '***account for the entire period*** during which diligence is required.'" *Creative Compounds, LLC v. Starmark Labs.*, 651 F.3d 1303, 1312–13 (Fed. Cir. 2011) (quoting *Gould v. Schawlow*, 363 F.2d 908, 919

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upon because it was not copending with the Coleman '362 application. 35 U.S.C. § 120. Accordingly, . . . he was limited to his filing date of December 22, 1980, for a constructive reduction to practice."); 3A Donald S. Chisum, *Chisum on Patents* § 10.05 (2021) ("A filed patent application adequately describing the invention maintains its status as a constructive reduction to practice only so long as the applicant maintains continuity of prosecution. *The applicant may file continuation or divisional applications under Sections 120 and 121 and retain the benefit of the filing date of the original application as the date of constructive reduction to practice. However, if the applicant loses the benefit of the original filing date of an application . . . that filing date ceases to be a constructive reduction to practice and reverts to a status of evidence of conception.*") (emphasis added).

(C.C.P.A. 1966) (emphasis added)). Importantly, a party has not exercised reasonable diligence in reducing the invention to practice ***where there is unexplained inactivity prior to the opponent's entry into the field.*** *See Meyer*, 411 F. App'x at 319–20 (finding no reasonable diligence given "an unexplained gap of just over two months" in evidence of diligence); *Griffith v. Kanamaru*, 816 F.2d 624, 629 (Fed. Cir. 1987) (affirming grant of summary judgment of invalidity where Griffith could not show diligence for a three-month period, and thus "failed to establish a prima facie case of reasonable diligence or a legally sufficient excuse for inactivity to establish priority over Kanamaru") (emphasis added); *see also Fitzgerald v. Arbib*, 268 F.2d 763, 766 (C.C.P.A. 1959) (finding lack of diligence given a period of "unexplained inactivity" "as abbreviated as one to two months in duration").).

Here, there is no genuine dispute that MedComp cannot meet its burden of production with respect to diligence. In response to Bard's extensive discovery aimed at uncovering all of MedComp's alleged diligence evidence, MedComp identified a total of ***only eight documents,*** to prove its alleged diligence from Nov. 5, 2006 (just prior to Bard's submission of its 510(k)) to July 19, 2007 (the filing date of the '133 provisional). Specifically, Bard propounded interrogatories asking MedComp to "identify ***every document*** that you intend to rely on to support your alleged diligence" between its alleged conception and reduction to practice dates. SUMF 14-15; Ex. C at 8 (emphasis added). In response, MedComp identified eight emails that fall within the relevant diligence period. SUMF 23-26; Ex. D at 26. Because some of these emails are threads covering multiple days, these eight email reflect activity on a total of nine days in the diligence period.[8]

[8] Aside from the diligence evidence falling outside the critical period, MedComp also cited one unsigned, unwitnessed lab notebook with dates falling within the critical period.

Date(s) of Email	Exhibit
November 9, 2006	Ex. F
February 15, 2007	Ex. G at MED00071451-52
February 20, 2007	Ex. H at MED0071472
April 4, 2007	Ex. I
April 5, 2007	Ex. H at MED0071474
April 6, 2007	Ex. H at MED0071474
April 10, 2007	Ex. H at MED0071474
May 3, 2007	Ex. E; Ex. J; Ex. K;
May 30, 2007	Ex. L

Thus, as can be seen, MedComp has not come forward with any diligence evidence for the approximately three month period from November 9, 2006 to February 15, 2007. And MedComp came forward with evidence of diligence on only two days for the almost five month period from November 9, 2006 to April 4, 2007. Put differently, the period from November 5, 2006 to July 19, 2007 is 257 days. MedComp has come forward with evidence of diligence on only nine, or approximately 3.5%, of those days. Moreover, MedComp has offered no explanation for why, if it were in fact diligent in reducing its alleged invention to practice through the critical period, it can locate no evidence substantiating that claim. No reasonable

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SUMF ¶ 24. But MedComp's corporate designee testified that [redacted] *Id.* In addition, Federal Circuit case law consistently rejects reliance on unsigned and undated lab notebooks. *See Procter & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 998-99 (Fed. Cir. 2009) (unwitnessed lab notebook "did not provide adequate corroborating evidence of an earlier invention date"); *Medichem, S.A. v. Rolabo*, S.L., 437 F.3d 1157, 1173 (Fed. Cir. 2006) (finding "insufficient as a matter of law to corroborate [] reduction to practice" lab notebooks that "ha[ve] not been signed or witnessed and ha[ve] not been maintained in reasonable accordance with good laboratory practices sufficient to reasonably ensure its genuineness under the circumstances").

factfinder could find that MedComp has met its burden of production under the applicable legal standard. *See Meyer*, 411 F. App'x at 319–20; *see also Brown*, 436 F.3d at 1380 ("[P]recedent requires that an inventor's testimony concerning his diligence be corroborated.").

Bard also served a Notice of Deposition of Medical Components pursuant to Rule 30(b)(6) requesting testimony on MedComp's diligence and the factual bases for MedComp's written discovery responses, including MedComp interrogatory response on diligence. MedComp's corporate designees [redacted] SUMF 32-34; Ex. O at 84:19-85:10. [redacted] SUMF 35; Ex. N at 113:2-124:11. Moreover, MedComp's corporate representative admitted that the documents produced in this case, and cited in its interrogatory response regarding diligence, [redacted] Ex. O at 83:20-22. Thus, MedComp's corporate witnesses confirm that it cannot meet its burden of production on diligence.

* * *

MedComp cannot as matter of law rely on the filing date of the '591 provisional for constructive reduction and has failed to carry its burden of production relating to diligence. The PowerPort MRI is therefore prior art under §102(g). The Court should thus hold that the PowerPort MRI anticipates claims 1, 19-20, 26, and 39-42 of the '324 patent.

CONCLUSION

For the foregoing reasons, Bard's motion for summary judgment of invalidity should be granted.

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Respectfully submitted,

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